



IP-37-001-0902

Information **Shipping ThinPrep® Solutions and Samples within**
Paper **CONUS**
 50-500 Vials – Limited Quantity Shipments
 July 2005

NOTE: If you are shipping less than 50 vials of Thin Prep (per package), please refer to the Fact Sheet for shipping 1-49 vials. This is available at <http://chppm-www.apgea.army.mil/hmwp/>; This Fact Sheet is applicable for 1-500 vials of Thin Prep but additional exceptions are allowed when shipping between 1-49 vials. If you need to ship greater than 500 vials per package, we suggest you break up the number of vials so that each package you send has a maximum of 500 vials each. This will enable you to use the limited quantity exception allowed by the Department of Transportation (DOT) as well as by the International Air Transport Association (IATA).

1. Background. Department of Defense (DOD) medical facilities collect and process specimens to test for cervical cancer using the ThinPrep® PreservCyt® solution made by the Cytoc Corporation. PreservCyt® is a methanol-based, buffered preservative solution and is classified as a hazardous material (HM) due to its low flashpoint (80°F/26.5°C) and must be packaged and shipped in accordance with regulatory requirements governing transport of HMs within the United States.
2. Training. Personnel who package any quantity of ThinPrep® solution must receive training, within 90 days of employment per 49 CFR 172.704 and International Air Transport Association (IATA) Regulations Chapter 1, Section 1.5. All personnel who sign hazardous materials shipping papers for ThinPrep® shipments must be formally trained per Defense Transportation Regulations, DOD Regulation 4500.9-R, Part II, Chapter 204, Section D (http://www.transcom.mil/j5/pt/dtrpart2/dtr_part_ii_204.pdf). Certification training can be obtained by successfully completing the Transport of Biomedical Material Course given by the U.S. Army Center for Health Promotion and Preventive Medicine. Registration for the Transport of Biomedical Material Course is available at <http://chppm-www.apgea.army.mil/trng>. This paper is not a substitute for the specialized training required.
3. Hazard Classification. New vials of PreservCyt® solution as well as those containing a specimen are Hazard Class 3, Flammable Liquids, based on the manufacturer's Material Safety Data Sheet. Although PreservCyt solution contains a biological specimen being sent for purposes of diagnosis, the sample IS NOT classified as a Diagnostic Specimen. PreservCyt solution contains chemicals that will neutralize any infectious agents that might be present. The specimen is therefore excepted from being classified as a Division 6.2 material based on 49 CFR Part 173.134(b)(2)
4. Basic Description: Flammable Liquids, n.o.s. (contains methanol), 3, UN1993, III.

5. Shipment: as a Limited Quantity: Limited quantity requirements are defined in 49 CFR 172.101, column 8A and IATA Regulations, Chapter 2, Section 2.8. New vials of PreservCyt® solution or specimens collected in PreservCyt® may be shipped as a limited quantity **provided each** inner receptacle (vial) does not contain more than 5L of solution. Each vial of Thin Prep holds 20 milliliters of solution.

a. Highway: The 49 CFR 172.101, Hazardous Materials Table, Column 8A (Exceptions) directs you to the appropriate section under 49 CFR Part 173 that determines the quantity limits and types of packaging that can be used to ship that particular HM. The proper shipping name “Flammable Liquids, n.o.s.,” lists three packing groups. ThinPrep is in PGIII. Column 8A of the Hazardous Materials Table directs you to section 173.150 for shipping Limited Quantities of Class 3 flammable liquids.

(1) Packaging: Each inner receptacle with a removable closure must be packaged so that closures of the inner containers are upright. The inner receptacles must be securely packed in cushioning material. Strong outer packagings that are able to withstand the rigors of transport must be used (49 CFR 173.150(b)(3), 171.8, 173.24, 173.24a). Under 49 CFR 173.150(b), you may ship PreservCyt® solution or specimens as a limited quantity as long as the weight of the completed outer packaging does not exceed 30 kg (66 pounds). In this case, the number of vials is not the limiting factor but the overall package weight.

(2) Marking and Labeling. The proper shipping name with the technical name [Flammable Liquid, n.o.s., (contains methanol)] must be marked on the outer packaging near the receiver’s name and address. The proper shipping name technical name can be replaced by a square on point border containing the UN ID 1993 as shown in Figure 1. Hazard labels and are not required.

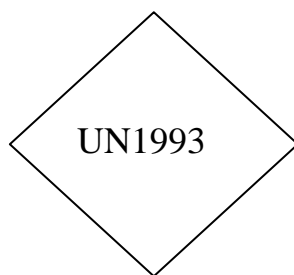


Figure 1

(3) Shipping Papers: A shipping paper is required. If the shipment is transported by government courier over public highways use a DD836, Dangerous Good Shipping Paper as the hazardous material shipping paper. Complete the form in accordance with the instructions found in the DOD 4500.9-R, Part II, Chapter 204. A bill of lading may be used to document the commercial ground transport (highway) shipment. Complete the hazardous material shipping paper as outlined in 49 CFR 172.200 through 172.205 and put the words “Limited Quantity” after the basic description [49 CFR 172.203(b)]. No emergency response number is required on the shipping paper [49 CFR 172.604(c)(1)]. No placards are required.

b. Commercial air: New vials of PreservCyt® solution or specimens collected in PreservCyt® may be shipped as a limited quantity as defined in the IATA Regulations, Chapter 2, Section 2.8. Chapter 4 of the IATA, the Dangerous Goods List, directs you to the proper packing

instruction to determine the quantity limits and types of packaging that can be used to ship PreservCyt®.

(1) Packaging: Flammable liquids, n.o.s. (PGIII), directs you to Packing Instruction Y309 for limited quantity shipments. The inner receptacles must be securely packed with sufficient cushioning/absorbent material. Outer packagings must pass the drop and stacking test required under IATA 2.8.5. Under IATA Section 2.8.4, you may ship PreservCyt® solution or specimens as a limited quantity as long as the total outer packaging weight does not exceed 30 kg (66 pounds). The maximum quantity permitted in one outer packaging is 10,000 mL (10L). A maximum of 500 of the 20mL vials may be shipped in one package as a limited quantity as long as the weight of the completed outer packaging does not exceed 30 kg (66 pounds).

(2) Marking and Labeling: Mark the proper shipping name (with technical name), UN ID number and “LTD QTY” or “LIMITED QUANTITY” on the outer packaging near the receiver’s full name and address (IATA Section 7.1.5). Mark the shipper’s full name and address on the outer packaging. Package orientation markings are not required (IATA 7.2.4.4). Labeling is required. Affix Flammable Liquid (Hazard Class 3) label to the outer packaging on the same surface as the proper shipping name, near the receiver’s address. [Both the shipper’s and receiver’s full names and addresses must be marked on the outer package when shipping by commercial air.]

(3) Shipping Papers: A shipper’s declaration for dangerous goods and an Air Waybill are required. Complete the shipper’s declaration for dangerous goods according the instructions found in IATA Chapter 8, Section 8.1.6. Remember to put the words “Limited Quantity” or “Ltd Qty” in the column for Authorizations. Complete the Air Waybill per the carrier’s instructions.

6. For waste management issues, procedures and regulatory requirements see USACHPPM Fact Sheet, Management of Waste from the ThinPrep® Processor, <http://chppm-www.apgea.army.mil/hmwp/> then Facts Sheets, Hazardous Waste.

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